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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/676,670	10/02/2000	George H. Scherr	CU-3758	4775

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EXAMINER	
SHARAREH, SHAHNAM J	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/676,670	SCHERR, GEORGE H.	
	Examiner	Art Unit	
	Shahnam Sharareh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/17/2005, 10/14/2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-151 and 153* is/are pending in the application.

4a) Of the above claim(s) *20-76* is/are withdrawn from consideration.

5)☒ Claim(s) *77-90 and 105-123* is/are allowed.

6)☒ Claim(s) *91-104,124-151 and 153* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 12, 2004, April 20, 2005, June 14, 2005, June 17, 2005 have been entered.

Prosecution History

2. The originally filed claims 1-54 were subject to a Restriction Requirement on January 29, 2002. Applicant elected claims 1-19 without traverse in Paper No. 3, filed on December 25, 2002.

3. Claims 20-76 were held withdrawn from consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention as being directed to such process with different modes of operation, and there being no allowable generic or linking claim. (see Paper Nos. 2, 4 and 6).

4. Claims 77-90 were declared allowable in Paper No. 6 filed on October 22, 2002.

5. Claims 91-104 were rejected under 35 U.S.C. 102(b) as being anticipated by Scherr US Patent 5,718,916 or Patel US Patent 5,470,576 in Paper No. 6 because claims 91-104 are drafted as "product by process" and Scherr and Patel were deemed to meet the limitations of claims 91-104 for the reasons of record set for in Paper No. 6, filed on October 22, 2002. The Paper No. 6 was issued as the Final Rejection on merits

of then pending claims, because the rejection of record was necessitated by Applicant's amendment filed on July 12, 2002, Paper No. 5.

6. Claims 105-149 were then presented in Paper No. 7/B, filed on January 14, 2003 in response to the Paper No. 6 Final Rejection.

7. Claims 105-149 were properly not entered because Paper No. 7/B failed to reduce or simplify the issues for appeal. In addition, the amendment seemed to raise new issues.

8. Pursuant to the petition filed on July 07, 2003 and the Grant of said Petition on September 24, 2003, Paper No. 12, the application was revived and the finality of the Paper No. 6 was withdrawn. Claims 104-149 were entered to merely simplify the status of the pending claims. Nevertheless, the issues remained the same as in Paper No 7/B.

9. Claims 20-149 stood pending. Claims 20-76 were withdrawn from consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention as being directed to such process with different modes of operation, and there being no allowable generic or linking claim. (see Paper Nos. 2, 4 and 6).

10. Claims 77-90, 105-123 were declared free of art and thus are allowable.

11. Claims 20-151, 153 are now pending. Claims 20-76 stand withdrawn. Claims 77-90, 105-123 are free of art.

12. Any rejection that is not addressed in this Office Action is considered obviated in view of Applicant's arguments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

13. Claims 91-104 stand rejected under 35 U.S.C. 102(b) as being anticipated by Scherr US Patent 5,718,916 or Patel US Patent 5,470,576.

14. Claims 91-104 are drafted as "product by process." Products by process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps (see MPEP 2113). "Even though product - by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product - by - process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe* , 227 USPQ 964, 966 (Fed. Cir. 1985).

15. The instant claims are directed to a water insoluble alginate sponge or foam. As reasoned above, claims are drafted in the form of product by process and process of preparing the product does not impart patentability of the product itself.

16. Scherr discloses water insoluble alginate sponges (abstract, examples 6-8, col 11-12). The claimed sponges are not elementally different than those of Shcerr.Thus, Scherr anticipates the limitations of the instant claims.

17. Patel teaches the use of similar alginate compositions as wound dressings on absorbent pad or bandages by impregnating the with the alginate composition (see abstract, col 7, lines 4-60). The compositions of Patel are not elementally different than those instantly claimed. Thus, Patel anticipates the limitations of the instant claims.

18. Claims 91-104, 228,, 131, 134,143-151, 153 stand rejected under 35 U.S.C. 102(e) as being anticipated by Gilding US Patent 5,998,692.

Gilding teaches wound dressings comprising silver alginate or zinc alginate (see col 2, lines 1-4, col 4, lines 6-11). Gilding's composition also contains copper alginate or copper borate (col 4, lines 29-33). Copper borate of Gidling reads on the medicinal agent of the instant claims. Thus, Gilding anticipates the limitations of the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

19. Claims 91-104, 124-151, 153 stand ejected under 35 U.S.C. 103(a) as being unpatentable over Bakis US Patent 5,851,461 in view of Patel US Patent 5,470,576 and/or Scherr US Patent 5,718,916 .

20. Bakis teaches sodium or calcium alginate foams, pads or gauzes that can comprise at least an additional medicinal agent such as cells to be implanted in a human or animal body (see abstract, col 6, lines 35-67; examples 1-5). Bakis fails to specifically enumerate various medicinal agents such as antibacterial, antibiotics or even the use of other di- or tri-valent alginate salts such as silver.

21. Patel provides that zinc alginate or silver alginates are well-recognized art equivalent tri-valent alginate salts that may be used in the art of sponge dressings. (see col 3, lines 14-26).

22. Scherr provides for incorporation of various sorts of medicinal agents such as antibacterial, antibiotics, etc.. into a topical surgical dressing, foam or sponge to improve therapeutic benefits. (see abstract, col 11, lines 2-10).

23. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to add a suitable medicinal agent or use a suitable alginate salt in

formulations of Bakis, because as shown by Patel, using art equivalent alginate salt, and/or further, as provided by Scherr, using a suitable medicinal agent in a surgical dressing to improve therapeutic benefits would have been an obvious modification of Bakis' dressings.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

24. Claims 91-104, 139-151, 153 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 30 of U.S. Patent No. 6,696,077. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to compositions comprising silver or calcium alginate.

The pending claims are directed to water-insoluble alginate sponge comprising calcium alginate or silver alginate sponge. The patented claims are directed to sponges or moieties comprising silver or calcium alginates. Accordingly, the scope of the pending claims overlaps with those of the patented claims. It would have been obvious to one of

ordinary skill in the art at the time of invention to practice the pending claims once in possession of the patented claims.

Response to Arguments

25. Applicant's arguments filed October 12, 2004 have been fully considered but they are not persuasive, because they are not commensurate with the scope of the claims.

Applicant's arguments primarily are directed to one line of reasoning. Applicant argues that none of the cited references teach the exact process as instantly employed to make the claimed products. Examiner states again, as it has been repeatedly articulated during the prosecution of this case, the instantly presented product claims are drafted in the form of PRODUCT BY PROCESS claims. Accordingly, their patentability is based on the product itself. Applicant is urged to review MPEP § 2113 for a better understanding for the scope interpretation of such claims.

Further, the instantly recited process steps do not produce any expressed or implied structural limitations that is away from the cited references. In another word, the only way that the claimed products can be defined **is not** by their preparation steps. Neither does the manufacturing process steps create a distinctive structural characteristic in the final claimed product that can be only expressed by the recitation of process steps. (see the holding of *In re Garnero*, 412, F2d 276, 162, USPQ 221, 223 (CCPA 1979).

In addition, the attributions articulate in the page 19 of the Applicant's Response filed on October 10, 2004 have no basis in the pending rejected claims and are not

found to commensurate with the scope of the claims. For example, consider the instant claims 150 and 153. The claims respectively read: " A silver alginate wound dressing," and " A silver alginate moiety." None of applicant's arguments are commensurate with the scope of such claim, because not only any silver alginate moiety reads on the scope of this claim regardless of how the silver alginate moiety is prepared, but also the claim on its face is simply not limited to any argued attributes that may not be found in the cited references.

With respect to claims 91-104, Examiner states that the claims are directed to a water-insoluble sponge prepared by methods of claim 77-89. Again, there are not any indicated limitations that the claimed product possesses a distinctive structural characteristic than those of prior art. Nor is there any indication that the products of Scherr or Pattel or Bakis cannot be made by the instant process of claims 77-89. If such prior art products, namely Scherr, Pattel or Bakis, can be made by the instantly claimed process, then they anticipate the instant product claims 91-104, because they are water-insoluble alginate sponge prepared by the instantly claimed process of claims 77-90.

26. Examiner is simply at loss as how to convey this message. Should Applicant find that a personal or telephonic interview could simplify or improve Applicant's understanding of Examiner's position, Applicant is encouraged to contact and schedule an interview.

Conclusion

In conclusion, at this time, claims 77-90, 105-123 are allowable.

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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SREENI PADMANABHAN
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